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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/821,151	04/07/2004		020366

CONFIRMATION NO. 8963

## FORMALITIES LETTER



\*OC000000013020885\*

26285  
 KIRKPATRICK & LOCKHART LLP  
 535 SMITHFIELD STREET  
 PITTSBURGH, PA 15222

Date Mailed: 06/22/2004

## NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

08/19/2004 HALI11 00000028 10821151

FILED UNDER 37 CFR 1.53(b)

01 FC:1051

130.00 DP

*Filing Date Granted*Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing.  
*A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121 are required. The drawings submitted are not acceptable because:
  - The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 5A, 7A, 10 & 11.

SUMMARY OF FEES DUE:


Total additional fee(s) required for this application is **\$130** for a Large Entity

- **\$130** Late oath or declaration Surcharge.

Replies should be mailed to: Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

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*A copy of this notice **MUST** be returned with the reply.*

  
Customer Service Center  
Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Keusch et al.

Application No.: 10/821,151

Filed: April 7, 2004

**For: ELECTRICALLY-ASSISTED LIDOCAINE AND EPINEPHRINE DELIVERY DEVICE  
HAVING EXTENDED SHELF- STABILITY**

**Mail Stop: Missing Parts**

**Commissioner for Patents**

**P.O. Box: 1450**

**Alexandria, VA 22313-1450**

**EXPRESS MAIL CERTIFICATE**

"Express Mail" label number ED153381935US

Date of Deposit August 17, 2004

I hereby certify that the following attached paper or fee

**COMPLETION OF FILING REQUIREMENTS-NONPROVISIONAL APPLICATION**

**COPY OF PTO FORM-1533**

**DECLARATION (3 Sets)**

**3.73 (b) STATEMENT WITH COPY OF EXECUTED ASSIGNMENT**

**10 REPLACEMENT DRAWING SHEETS**

**CHECK PAYABLE TO PTO**

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: **Mail Stop: Missing Parts, Commissioner for Patents  
P.O. Box: 1450, Alexandria, VA 22313-1450**

Beth H. Retort

(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)

**NOTE:** Each paper must have its own certificate and the "Express Mail" label number as a part thereof or attached thereto. When, as here, the certification is presented on a separate sheet, that sheet must (1) be signed and (2) fully identify and be securely attached to the paper or fee it accompanies. Identification should include the serial number and filing date of the application as well as the type of paper being filed, e.g. complete application, specification and drawings, responses to rejection or refusal, notice of appeal, etc. If the serial number of the application is not known, the identification should include at least the name of the inventor(s) and the title of the invention.

**NOTE:** The label number need not be placed in each page. It should, however, be placed on the first page of each separate document, such as, a new application, amendment, assignment, and transmittal letter for a fee, along with the certificate of mailing by "Express Mail." Although the label number may be on checks, such a practice is not required. In order not to deface formal drawings it is suggested that the label number be placed on the back of each formal drawing or the drawings be accompanied by a set of informal drawings on which the label number is placed.

**(Express Mail Certificate [8-3])**



Practitioner's Docket No. 020366

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Keusch et al.

Application No.: 10/821,151

Filed: April 7, 2004

For: ELECTRICALLY-ASSISTED LIDOCAINE AND EPINEPHRINE DELIVERY DEVICE  
HAVING EXTENDED SHELF- STABILITY

Mail Stop: Missing Parts  
Commissioner for Patents  
P.O. Box: 1450  
Alexandria, VA 22313-1450

COMPLETION OF FILING REQUIREMENTS  
— NONPROVISIONAL APPLICATION

(check and complete this item, if applicable)

- I. ☒ This replies to the Notice to File Missing Parts of Application (PTO-1533) mailed  
June 22, 2004.

NOTE: If these papers are filed before the office letter issues, adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the serial number from the return post card or the attorney's docket number added.

- ☒ A copy of the Notice to File Missing Parts of Application—Filing Date  
Granted (Form PTO-1533) is enclosed.

NOTE: The PTO requires that a copy of Form PTO-1533 be returned with the response to the notice to file missing parts to the application.

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is, on the date shown below, being:

MAILING

- ☐ deposited with the United States Postal  
Service with sufficient postage as first  
class mail in an envelope addressed to:  
Box: Missing Part, Commissioner for  
Patents, P.O. Box: 1450, Alexandria,  
VA 22313-1450.

FACSIMILE

- ☐ transmitted by  
facsimile to the Patent  
and Trademark Office.

Signature

Date: \_\_\_\_\_

\_\_\_\_\_  
(type or print name of person certifying)

## DECLARATION OR OATH

- II. ☒ No declaration or oath was filed. Enclosed is the original declaration or oath for this application.

*NOTE: If the correct inventor or inventors are not named on filing a nonprovisional application under § 1.53(b) without an executed oath or declaration under § 1.63, the later submission of an executed oath or declaration under § 1.63 during the pendency of the application will act to correct the earlier identification of inventorship. 37 C.F.R. § 1.48(f)(1).*

## OR

- ☐ The declaration or oath that was filed was determined to be defective. A new original oath or declaration is attached.

*NOTE: For surcharge fee for filing declaration after filing date complete item VI(3) below.*

*NOTE: "The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 C.F.R. 1.63:*

*"(1) name of inventor(s), and application number (consisting of the series code and the serial number; e.g., 08/123,456);*

*"(2) name of inventor(s), serial number and filing date;*

*"(3) name of inventor(s) and attorney docket number which was on the specification as filed;*

*"(4) name of inventor(s), title which was on the specification as filed and filing date;*

*"(5) name of inventor(s), title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or*

*"(6) name of inventor(s), title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number; e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration."*

*Notice of Jul. 13, 1995 (1177 O.G. 60); M.P.E.P. § 601.01(a), 6<sup>th</sup> ed., rev. 3.*

*NOTE: Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 C.F.R. 1.10(c).*

*(complete (c) or (d), if applicable)*

Attached is a

- (c) ☐ Statement by a registered attorney that the application filed in the PTO is the application that the inventor executed by signing the declaration.
- (d) ☐ Statement that the "attached" specification is a copy of the specification and any amendments thereto that were filed in the PTO to obtain the filing date.

## AMENDMENT CANCELLING CLAIMS

- III. ☐ Cancel claims \_\_\_\_\_ inclusive.

**TRANSMITTAL OF ENGLISH TRANSLATION  
OF NON-ENGLISH LANGUAGE PAPERS**

- IV. ☐ Submitted herewith is an English translation of the non-English language application papers as originally filed. Also submitted herewith is a statement by the translator of the accuracy of the translation. It is requested that this translation be used as the copy for examination purposes in the PTO.

*NOTE: For fee processing a non-English application, complete item VI(5) below.*

*NOTE: A non-English oath or declaration in the form provided by the PTO need not be translated. 37 C.F.R. 1.69(b).*

**SMALL ENTITY STATUS**

- V. ☐ A statement that this filing is by a small entity is hereby asserted in accordance with the rule change effective September 8, 2000, 65 Fed. Reg. 54603.

**COMPLETION FEES**

**VI.**

*WARNING: Failure to submit the surcharge fees where required will cause the application to become abandoned. 37 C.F.R. 1.53.*

*NOTE: For effect on fees of failure to establish status, or change status, as a small entity, see 37 C.F.R. 1.28(a).*

**1. Filing fee**

- ☐ original patent application  
(37 C.F.R. 1.16(a)—\$770.00; Small entity—\$385.00)\$ \_\_\_\_\_
- ☐ design application  
(37 C.F.R. 1.16(f)—\$340.00; small entity—\$170.00)      \$ \_\_\_\_\_  
\$ \_\_\_\_\_

**2. Fees for claims**

- ☐ each independent claim in excess of 3  
(37 C.F.R. 1.16(b)—\$86.00; small entity—\$43.00)      \$ \_\_\_\_\_
- ☐ each claim in excess of 20  
(37 C.F.R. 1.16(c)—\$18.00; small entity—\$9.00)      \$ \_\_\_\_\_
- ☐ multiple dependent claim(s)  
(37 C.F.R. 1.16(d)—\$290.00; small entity—\$150.00)      \$ \_\_\_\_\_

### 3. Surcharge fees

☐ late payment of filing fee

and/or

☒ late filing of original declaration or oath  
(37 C.F.R. 1.16(e)—\$130.00; small entity—\$65.00); \$ 130.00

*NOTE: Even where a facsimile declaration or oath signed by the inventor(s) was part of the originally filed papers, the surcharge fee is required.*

*NOTE: If both the filing fee and declaration or oath were missing from the original papers, only one surcharge fee for both need be paid. 37 C.F.R. 1.16(e).*

4. ☐ Petition and fee for filing by other than all the inventors  
or a person not the inventor (37 C.F.R. 1.17(i) and  
1.47—\$130.00) \$ \_\_\_\_\_

5. ☐ Fee for processing an application filed with a  
specification in a non-English language  
(37 C.F.R. 1.17(k) and 1.52(d)—\$130.00) \$ \_\_\_\_\_

6. ☐ Fee for processing and retention of application  
(37 C.F.R. 1.21(l) and 1.53(d)—\$130.00) \$ \_\_\_\_\_

7. ☐ Assignment (See "ASSIGNMENT COVER SHEET".)

*NOTE: 37 C.F.R. 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 C.F.R. 1.53(f) and this, as well as, the changes to 37 C.F.R. 1.53 and 1.78 indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee or the processing and retention fee of § 1.21(l) within 1 year of notification under § 1.53(f) must be paid.*

Total completion fees \$ 130.00

### EXTENSION OF TIME

#### VII.

(complete (a) or (b), as applicable)

The proceedings herein are for a patent application, and the provisions of 37 C.F.R. 1.136(a) apply.

(a) ☐ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. 1.17(a)(1)-(4), for the total number of months checked below:

Extension (months)	Fee for other than small entity	Fee for small entity
<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 420.00	\$210.00
<input type="checkbox"/> three months	\$ 950.00	\$475.00
<input type="checkbox"/> four months	\$1,480.00	\$740.00
<input type="checkbox"/> five months	\$2,010.00	\$1,005.00
		<b>Fee \$</b>

If an additional extension of time is required, please consider this a petition therefor.  
(check and complete the next item, if applicable)

- ☐ An extension for \_\_\_\_ months has already been secured, and the fee paid therefor of \$ \_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$

or

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

#### TOTAL FEE DUE

#### VIII.

The total fee due is

Completion fee(s) \$ 130.00  
Extension fee (if any) \$ 0

**Total Fee Due \$130.00**

#### PAYMENT OF FEES

#### IX.

- ☒ Enclosed is a check in the amount of \$ 130.00
- ☐ Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_  
A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. 1.22(b).

Please charge Account No. 11-1110 for any fees that may be due by this paper.

#### AUTHORIZATION TO CHARGE ADDITIONAL FEES

#### X.

**WARNING:** Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

- ☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the pendency of this application to Account No. 11-1110.



- ☒ 37 C.F.R. 1.16(a), (f) or (g) (filing fees)
- ☒ 37 C.F.R. 1.16(b), (c) and (d) (presentation of extra claims)

*NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.*

- ☒ 37 C.F.R. 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
- ☒ 37 C.F.R. §§ 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a))
- ☒ 37 C.F.R. 1.17 (application processing fees)

*NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).*

- ☐ 37 C.F.R. 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. 1.311(b))

*NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. 1.311(b).*

*NOTE: 37 C.F.R. 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee . . ." From the wording of 37 C.F.R. 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.*

  
\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

Jesse A. Hirshman  
(type or print name of practitioner)

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